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IS 10058 (1985): Forceps, Fixation, Graefe's Pattern
(Modified) [MHD 5: Ophthalmic Instruments and Appliances]

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“Knowledge is such a treasure which cannot be stolen”



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Indian Standard
SPECIFICATION FOR
FORCEPS, FIXATION, GRAEFE'S
PATTERN (MODIFIED)
(*First Revision*)

UDC 615.472.4 : 617.7-089-72



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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Indian Standard

**SPECIFICATION FOR
FORCEPS, FIXATION, GRAEFE'S
PATTERN (MODIFIED)**

(First Revision)

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(*Continued on page 2*)

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Indian Standard

SPECIFICATION FOR
FORCEPS, FIXATION, GRAEFE'S
PATTERN (MODIFIED)

(First Revision)

0. F O R E W O R D

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 25 November 1985, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Consumer Products & Medical Instruments Division Council.

0.2 This standard was first published in 1981. The present revision has been taken up to include certain modifications in order to bring the specification in line with the modern manufacturing practices. In the revised standard the non-functional dimensions have been rounded off. The tolerance for the functional dimensions have been modified keeping in view the present manufacturing technique. A clause on sampling and inspection has been added. The test methods have been brought in line with the test methods covered in other similar standards of eye surgery instruments.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers requirements for Graefe's pattern fixation forceps used in eye surgery.

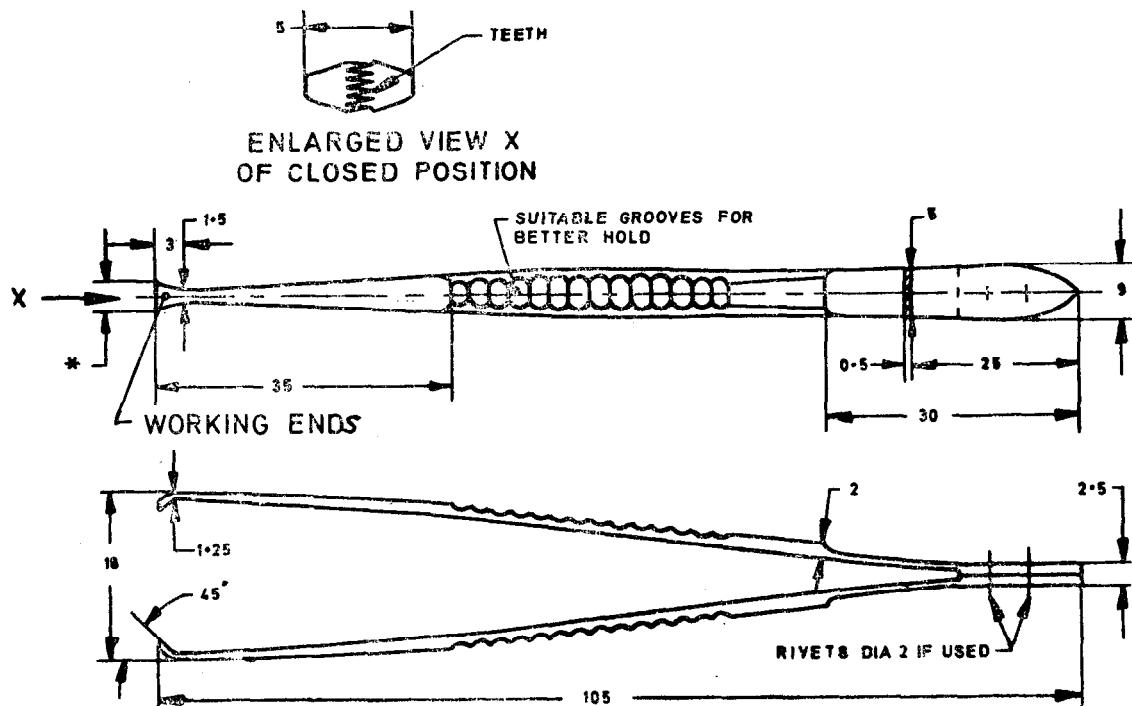
2. SHAPE AND DIMENSIONS

2.1 The shape and dimension shall be as shown in Fig. 1.

2.2 Joint — Shall conform to requirements given in 5 of IS : 3642-1978†.

*Rules for rounding off numerical values (*first revision*).

†General requirements for surgical instruments (*first revision*).



All dimensions in millimetres.

FIG. 1 FORCEPS, FIXATION, GRAEPE'S PATTERN

2.3 Teeth — Shall conform to requirements given in Section 4 of IS : 3642-1978* combination being 1 in 2, 2 in 3, 3 in 4, or 5 in 6.

2.4 The tolerance on dimensions of working ends shall conform to 'fine' class of deviation and the tolerance for remaining dimensions shall conform to 'medium' class of deviations of IS : 2102 (Part 1)-1980†.

3. MATERIAL

3.1 The material for forceps shall be stainless steel conforming to designation 30Cr 13 of IS : 6603-1972‡.

4. REQUIREMENTS

4.1 The forceps shall be finished smooth and shall be free from burrs, pits, cracks, and other surface defects.

4.2 The edges shall be even and rounded off.

4.3 The teeth shall be clear, clean and match perfectly.

4.4 The forceps shall be matt finished and passivated.

5. HARDNESS

5.1 The forceps shall be hardened and tempered to give a hardness of 400 to 460 HV.

6. TESTS

6.1 Test for Engagement of Teeth — A latex sheet of 0.05 mm thickness conforming to IS : 5430-1981§ be stretched over the tip of the fingers. The stretched latex sheet shall then be gripped by the teeth of the forceps and pulled to a distance of 6 mm. The forceps shall hold the latex sheet firmly without any tendency to slipping and the latex sheet shall not be punctured or damaged.

6.2 Flexibility Test — The arms of the forceps after maximum closure by manual compression shall not take a permanent set and the teeth shall continue to engage and disengage accurately and properly.

6.2.1 By the application of force at the tip of one arm, the arm of the forceps shall be deflected in a plane at right angles to the plane of the arm, by 20 mm as measured at the tip of the forceps. On release of the force no permanent set shall be observed. The test shall be repeated on the other arm.

*General requirements for surgical instruments (*first revision*).

†General tolerances for dimensions and form and position: Part 1 General tolerances for linear and angular dimensions (*second revision*).

‡Specification for stainless steel bars and flats.

§Specification for ammonia preserved concentrated natural rubber latex (*first revision*).

6.3 Corrosion Resistance Test — The forceps shall satisfy boiling and autoclaving test as specified in IS : 7531-1975*.

6.4 Load Closure Test — The load $215 \text{ g} \pm 20 \text{ g}$ when applied at a distance of 45 mm from the tips of the jaws shall make the teeth to just interlock.

7. SAMPLING AND CRITERIA FOR CONFORMITY

7.1 A suitable sampling scheme and criteria for acceptance is given in Appendix A.

8. MARKING

8.1 Each instrument shall be marked with the manufacturer's name, initials or recognized trade-mark and the word 'stainless steel' or letters 'SS'.

8.1.1 The forceps may also be marked with ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

9. PACKING

9.1 As agreed to between the purchaser and the supplier.

A P P E N D I X A

(Clause 7.1)

SAMPLING AND CRITERIA FOR CONFORMITY FOR FORCEPS

A-1. LOT

A-1.1 In any consignment, all the forceps produced from the same material, shape and dimensions under similar conditions, shall constitute a lot.

A-2. The number of forceps to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

*Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments.

TABLE 1 SCALE OF SAMPLING
(Clause A-2)

LOT SIZE (1)	SAMPLE SIZE (2)
Up to 15	2
16 ,, 50	3
51 ,, 150	5
151 and above	8

A-2.1 These forceps shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905-1968* may be followed.

A-3. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the forceps selected at random in accordance with col 1 and 2 of Table 1 shall be tested for hardness, requirements load closure, engagement of teeth, flexibility, and corrosion resistance. The lot shall be considered as conforming to these requirements if none of the forceps in the sample is found to be defective in any of these tests.

*Methods for random sampling.

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

QUANTITY	UNIT	SYMBOL
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

QUANTITY	UNIT	SYMBOL
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

QUANTITY	UNIT	SYMBOL	DEFINITION
Force	newton	N	1 N = 1 kg.m/s ²
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m ²
Frequency	hertz	Hz	1 Hz = 1 c/s (s ⁻¹)
Electric conductance	siemens	S	1 S = 1 A/V
Electromotive force	volt	V	1 V = 1 W/A
Pressure, stress	pascal	Pa	1 Pa = 1 N/m ²